Reproductive Health Specialists, LTD.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the above FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows. Quarantining embryos will not only significantly decrease the success rate for donor IVF (50%), but will also significantly increase costs and the number of cycles needed to obtain the same pregnancy rate. Because about half of the embryos do not survive the thawing process, there will be unnecessary deaths of embryos from the proposed rules to mandate freezing. It is estimated that approximately **9,000** embryos will be lost per year, representing a terrible loss of biological material and potential human lives. Additionally, increased delay causes anxiety and possible increased health risk in the woman delaying childbirth.

Please do not make embryo freezing mandatory for donor IVF-ET cycles as this will have a definite negative impact on those couples whose options are already limited.

Sincerely,

Marek W. Piekos, M.D.
MP/jm

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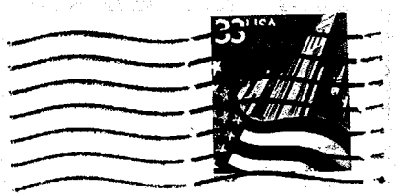

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